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JUL 17 2006

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PATENT ABSTRACTS OF JAPAN

(11)Publication number : 08-183566

(43)Date of publication of application : 16.07.1996

(51)Int.Cl.

B65D 81/24

A61B 17/12

A61B 19/02

(21)Application number : 06-326752

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(22)Date of filing : 28.12.1994

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(54) METHOD FOR PACKAGING MEDICAL IMPLEMENT MADE OF RUBBER

(57)Abstract:

PURPOSE: To prevent rubber deterioration due to ozone, etc., and achieve long preservation, by a method in which a medical implement, made of rubber having specific breaking extension rate and permanent set, is held in a state of being extended by higher than or equal to the breaking extension rate of the rubber and then it is hermetically sealed into a packaging container made of a material having specific oxygen permeability.

CONSTITUTION: A medical implement comprising rubber having a breaking extension rate of 500% or more and a permanent set of 20% or less is held in position while extended to 20% or higher than the breaking extension rate of the rubber, and it is stored into a packaging container (or packaging bag) made of a material whose oxygen permeability is 1cm³/m².atm.24hr or less. Alternately it is stored in a packaging container made of a material whose oxygen permeability is 10cm³/m².atm.24hr and a deoxidizing agent is sealed in as necessary. Or otherwise, when the implement is packaging, an inactive gas is substituted for air in the packaging container or vacuum is produced in the pack by letting the air out. As the rubber material, material, rubber, isoprene rubber, butadiene rubber, styrene-butadiene rubber or the like is used.

LEGAL STATUS

[Date of request for examination] 10.02.2000

[Date of sending the examiner's decision of rejection]

[Kind of final disposal of application other than the
examiner's decision of rejection or application converted
registration]

[Date of final disposal for application]

[Patent number] 3280182

[Date of registration] 22.02.2002

[Number of appeal against examiner's decision of rejection]

[Date of requesting appeal against examiner's decision of
rejection]

[Date of extinction of right]

JP,08-183566,A [CLAIMS]

1/1 ページ

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CLAIMS

[Claim(s)]

[Claim 1] The package approach of the medical supply made of rubber characterized by holding the medical supply which consists of rubber which has 500% or more of rates of elongation after fracture, and the property of 20% or less of permanent sets after 20% or more of rates of elongation after fracture of the rubber concerned has developed, containing it into the container or package bag with which oxygen gas transmittance consists of 1 cm³/m², atm, and a material of 24 or less hrs, and sealing it.

[Claim 2] The package approach of the medical supply made of rubber given in a claim (1) characterized by permuting the air in a container or a package bag with inert gas.

[Claim 3] The package approach of the medical supply made of rubber given in a claim (1) characterized by discharging the air in a container or a package bag, and considering as a vacuum packaging.

[Claim 4] The package approach of the medical supply made of rubber which encloses a deoxidant and is characterized by sealing while oxygen gas transmittance contains the medical supply made of rubber in the condition indicated by the claim (1) of having been elongated, into the container or package bag which consists of 10cm³/m², atm, and a material of 24 or less hrs.

[Claim 5] The package approach of the medical supply made of rubber given in either of the claims (1) thru/or claims (4) characterized by containing the medical supply made of rubber in the condition indicated by the claim (1) of having been elongated, to the PE liner of gas permeability in which the gas sterilization of contents is possible, and containing into the small outside bag of oxygen gas transmittance after closing opening and giving gas sterilization.

[Claim 6] The package approach of the medical supply made of rubber given in either of the claims (1) thru/or claims (5) characterized by a rubber ingredient consisting of one sort or two sorts or more of combination chosen from natural rubber, polyisoprene rubber, butadiene rubber, a styrene butadiene rubber, nitrile rubber, chloroprene rubber, and isobutylene isoprene rubber.

[Claim 7] The package approach of the medical supply made of rubber given in either of the claims (1) thru/or claims (6) to which the medical supply made of rubber is beforehand extended and extended to 200% or more, equips the periphery of a tubular object, and is characterized by being the O ring used for the circsodesis way which ligates a varix endoscopically.

[Translation done.]

JP:08-183566,A [DETAILED DESCRIPTION]

1/3 ページ

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DETAILED DESCRIPTION

[Detailed Description of the Invention]

[0001]

[Industrial Application] This invention relates to the package approach excellent in shelf life and engine-performance maintenance of the medical supply made of rubber held in the condition of having been elongated.

[0002]

[Description of the Prior Art] A medical supply is READY-TO in recent years. The product of USE, i.e., a disposable medical supply, comes to be used briskly, and it is already sterilized in a manufacturer's phase, and these are applicable to an operation, treatment, etc. as they are, if a package is opened in medical institutions, such as a medical practitioner. If these medical supplies are in ** which needs an at least two to three-month room [about] retention period, and is used still in emergency by the usual delivery, the thing which is in a hospital and with which extent storage is carried out and an emergency is equipped is required, and if it can do for six months, also at the lowest, it will be required that it should have a shelf life for two years or more.

[0003] Generally natural rubber and synthetic rubber deteriorate according to an operation of oxygen and ozone, and will have shelf life only about two years by the usual package approach. Moreover, even if there is no example, so that the flume of saving maintaining at the condition of on the other hand having elongated rubber is completely conventionally good, and it is possible, degradation of rubber will become quick, and it cannot save only about three to six months.

[0004] Although for the same to be said of a medical supply, and only for the term of a guarantee of two years to also have the product supplied in the condition of not extending rubber by the longest, but to extend a retention period further processing according a front face to silicone or a fluorine agent or by carrying out chloridization was tried, depending on the art, original engine performance, such as the degradation of rubber, i.e., the fall of elasticity, and an increment in permanent compressive strain, might be reduced.

[0005]

[Problem(s) to be Solved by the Invention] This invention is what is going to offer the package approach which enables long-term preservation, without making degradation and performance degradation of the rubber which had become a problem conventionally start. In 20% or more of expanding condition of the rate of elongation after fracture of rubber which could not be produced commercially especially conventionally, the shelf life is raised by 4 to 8 times, and it aims at offering the package approach which makes it possible to make the engine performance hold for one year or more.

[0006]

[Means for Solving the Problem] This invention namely, the medical supply which consists of rubber which has 500% or more of rates of elongation after fracture, and the property of 20% or less of permanent sets Hold, after 20% or more of the rate of elongation after fracture of the rubber concerned has developed, and it contains into the container or package bag with which oxygen gas transmittance consists of 1cm³/m², atm, and a material of 24 or less hrs. Or while oxygen gas transmittance contains into the container or package bag which consists of 10cm³/m², atm, and a material of 24 or less hrs, it is the package approach of the medical supply made of rubber characterized by enclosing and sealing a deoxidant.

[0007] Moreover, after containing inert gas permuting the air in a container or a package bag, or discharging air, and considering as a vacuum packaging at the time of the package by the above-mentioned approach, and the medical supply made of the rubber in the condition of having been elongated further, to the PE liner of gas permeability in which the gas sterilization of contents is possible, closing opening and giving gas sterilization, the package approach contained into a bag is also included in this invention outside the above with small oxygen-gas transmittance.

[0008] Furthermore, packing the O ring used for the circsodesis way which is beforehand extended and extended to 200% or more, equips the periphery of a tubular object, and ligates a varix endoscopically by the approach of this invention is included as a concrete desirable example of this invention.

[0009] As a ** rubber ingredient which constitutes the medical supply set as the object of a package in this invention, it is used in natural rubber, polyisoprene rubber, butadiene rubber, a styrene butadiene rubber, nitrile rubber, chloroprene rubber and the simple substances chosen from isobutylene isoprene rubber, or two or more kinds of those combination, these are further made into a principal component depending on the case, and NBR, SBR, silicone rubber, etc. may be blended.

[0010] The so-called rubber elasticity object said to usual as the rubber used here, i.e., Stress, Strain It is the rubber elasticity object which there is no hysteresis at Curve and the recuperability with time recovers 90% or more momentarily, and, as for the rate of elongation after fracture, what has 700% or more of elongation is preferably desirable 500% or more. Moreover, a permanent set should just be the natural rubber or synthetic rubber which has 15% or less of rate of low residual strain preferably 20% or less.

JP,08-183566,A [DETAILED DESCRIPTION]

2/3 ページ

[0011] Furthermore, when the medical supply which consists of such rubber is held at the condition of having been elongated [at least 20% or more of the rate of elongation after fracture] 250% or more depending on the case 50% or more or at least 100% or more depending on the case, and is actually used and a maintenance condition is opened wide, it returns to the condition before the original expanding mostly in an instant. What is used for applications, such as an O ring used for ligation of an esophageal varix, a polyp, the gun focus, etc., for example and a trigger which made rubber power, as the example is mentioned.

[0012] Ligation of an esophageal varix is an operation which is in the condition which the diameter of 6-15mm was made to elongate, equips with the O ring made of rubber with a bore [of 1.5-2.5mm], and an outer diameter of about 2.5-7.0mm the tubed device attached at the tip of an endoscope, thrusts down an O ring from a device to the varix attracted in the device, hangs on the root headquarters of a varix which was attracted and became polyp-like, and is mechanically litigated by the shrinkage force of the rubber of an O ring.

[0013] The usual medical supply needs at least to use an ingredient with the permeability which can penetrate gas to a part of package in order to sterilize by EOG (ethylene oxide gas) at the time of manufacture. Therefore, when the O ring made of rubber elongated with such a package gestalt is packed, a crack arises on the surface of an O ring in about three months, an O ring goes out during a medical practitioner's treatment depending on the case, and there is a danger of leading to big accident.

[0014] In order to prevent degradation of the rubber held in the condition of having been elongated, it is effective to use the container or package bag which consists of a material of 1cm³/m² of oxygen gas transmittance, atm, and the oxygen gas barrier property of 24 or less hrs. Moreover, if double, and inert gas, such as nitrogen gas, permutes the air in a container or a bag, or air is discharged and it is made a **** vacuum packaging, effectiveness will increase further.

[0015] As 1cm³/m², atm, and oxygen barrier property wrapping of 24 or less hrs, simple substances, such as a polyvinyl alcohol system film and a polyvinylidene chloride film, or a laminate film is mentioned for oxygen gas transmittance. Moreover, a silica vacuum evaporatio no polyethylene terephthalate film and a silica vacuum evaporatio no polyvinylidene chloride film are effective similarly. Although it has effectiveness with the same said also of an aluminum foil complex film and an aluminum vacuum evaporatio no film, transparency may be spoiled depending on a thing.

[0016] Moreover, when using the container or package bag with which oxygen gas transmittance consists of a material which has a little large oxygen gas permeability by 10cm³/m², atm, and 24 hrs or less, the same effectiveness is acquired by the approach of using a deoxidant together to this, and the desired end can be attained. Furthermore, if inert gas permutes the air in a container or a bag or a vacuum packaging is used together, of course, effectiveness increases more.

[0017] The film of the polypropylene with which oxygen gas transmittance carried out the coat of the polyvinylidene chloride, or compounded polyvinyl alcohol as 10cm³/m², atm, and wrapping of 24 or less hrs, or polyester, the simple substance film of a vinyl chloride or nylon or the film that vapor-deposited the silica to polyethylene terephthalate or nylon, and the multilayer film which combined these are mentioned. Moreover, in the case of the saccate thing, the good resin of heat-sealing nature, such as polyethylene and EVA, may be laminated inside at these. There is a film which is a multilayer film of polyethylene terephthalate or poly vinyl alcohol, and polyethylene, and prepared the vacuum evaporatio no layer of a silica between them as the example.

[0018] Next, although what used the activity iron oxide as the principal component is mentioned as a deoxidant used by this invention, it does not limit to especially this. When in the case of an activity iron oxide there is 22cm³ per g of oxygen absorbed of 3 and an oxygen density is made into 21%, although what is necessary is just the amount of a three or more 0.005 g/m deoxidant to the volume of a package object, it is good it to be more desirable to have taken the oxygen transmittance of wrapping etc. into consideration and to make [more / a little] it, and to enclose a three or more 0.007 g/m deoxidant with the package inside of the body.

[0019] These packages need to be made in the state of the full seal by saccate or the blister pack, and, in the case of a disposable medical supply, being sterilized is still more necessary. Therefore, when a medical supply is contained into a container or a package bag and EOG etc. performs the usual gas sterilization, after at least the part's consisting of materials of gas permeability, containing a medical supply to the PE liner in which gas sterilization is possible and giving gas sterilization, it is necessary to make it the duplex package contained into the small outside bag of oxygen gas transmittance.

[0020] In addition, when performing sterilization by the gamma ray or the electron ray, there is no need for a gas permeability package, and the one-step package by this application the first invention is enough. If a gamma ray and an electron ray are irradiated, generating of ozone will break out, but if the deoxidant is enclosed, ozone was absorbed by the effectiveness, it has also become clear that degradation of rubber hardly takes place, and it is more simple as the package approach.

[0021]

[Example] Into the silica vacuum evaporatio no bag using the film (1cm³/m² of oxygen gas transmittance, atm, and 24 hrs or less) by the configuration (polyethylene terephthalate 12micrometer / silica vacuum evaporatio no layer / polyethylene 60micrometer), what contained and carried out gas sterilization of the O ring made of polyisoprene rubber to the bag of the gas permeability in the condition of having elongated to 600%, with the bore of 2mm was put in and sealed, and it considered as the duplex package. When this was left under ozone 50pphm and an environment with a temperature of 40 degrees C, the crack etc. was not produced on an O ring front face after 72 hours (equivalent to the preservation during three years among air). Moreover, although the mothball trial saved for two years in air was performed, the crack etc. was not produced on an O ring front face. The effectiveness of the oxygen cutoff with a silica vacuum evaporatio no bag is clear.

JP,08-183566,A [DETAILED DESCRIPTION]

3/3 ページ

[0022]

[Comparative Example(s)] The same O ring as the example elongated to 600% was contained into the sterilization bag made of paper which has gas permeability, and was saved in air. One month after, a crack arises on an O ring front face, it will be in the condition that a part was going out, and an operation of the ozone in air or oxygen will show that degradation progresses quickly.

[0023]

[Effect of the Invention] Stabilization of quality can be attained, while being able to prevent degradation of the rubber by ozone etc. and enabling prolonged preservation by packing the medical supply made of rubber using the package approach of this invention.

[Translation done.]

METHOD FOR PACKAGING MEDICAL IMPLEMENT MADE OF RUBBER**Publication number:** JP8183566**Publication date:** 1996-07-16**Inventor:** SUZUKI ZENETSU; IZUMI YASUNOBU**Applicant:** SUMITOMO BAKELITE CO**Classification:****- International:** A61B17/12; A61B19/02; B65D81/24; A61B17/12;
A61B19/00; B65D81/24; (IPC1-7): B65D81/24;
A61B17/12; A61B19/02**- european:****Application number:** JP19940326752 19941228**Priority number(s):** JP19940326752 19941228**Report a data error here****Abstract of JP8183566**

PURPOSE: To prevent rubber deterioration due to ozone, etc., and achieve long preservation, by a method in which a medical implement, made of rubber having specific breaking extension rate and permanent set, is held in a state of being extended by higher than or equal to the breaking extension rate of the rubber and then it is hermetically sealed into a packaging container made of a material having specific oxygen permeability. **CONSTITUTION:** A medical implement comprising rubber having a breaking extension rate of 500% or more and a permanent set of 20% or less is held in position while extended to 20% or higher than the breaking extension rate of the rubber, and it is stored into a packaging container (or packaging bag) made of a material whose oxygen permeability is $1\text{cm}^3/\text{m}^2 \cdot \text{atm} \cdot 24\text{hr}$ or less. Alternately it is stored in a packaging container made of a material whose oxygen permeability is $10\text{cm}^3/\text{m}^2 \cdot \text{atm} \cdot 24\text{hr}$ and a deoxidizing agent is sealed in as necessary. Or otherwise, when the implement is packaging, an inactive gas is substituted for air in the packaging container or vacuum is produced in the pack by letting the air out. As the rubber material, material, rubber, isoprene rubber, butadiene rubber, styrene-butadiene rubber or the like is used.

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(19) 日本国特許庁 (J P)

(12) 公開特許公報 (A)

(11) 特許出願公開番号

特開平8-183566

(43) 公開日 平成8年(1996)7月16日

(51) Int.Cl. ⁶	識別記号	庁内整理番号	F I	技術表示箇所
B 6 5 D 81/24		D		
A 6 1 B 17/12				
19/02	5 0 5			

審査請求 未請求 請求項の数 7 O L (全 4 頁)

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(54) 【発明の名称】 ゴム製医療用具の包装方法

(57) 【要約】

【構成】 ゴム製の医療用具をその破断伸び率の20%以上に伸長された状態で保持し、酸素ガス透過度が $1\text{ cm}^3/\text{m}^2 \cdot \text{atm} \cdot 24\text{ hr}$ 以下の素材からなる包装容器に収納し、または、酸素ガス透過度が $10\text{ cm}^3/\text{m}^2 \cdot \text{atm} \cdot 24\text{ hr}$ 以下の素材からなる容器に収納すると共に、脱酸素剤を同封して、密封する。

【効果】 オゾン等によるゴムの劣化を防止して、長期間の保存を可能にすると共に、品質の安定化を図ることが出来る。

(2)

特開平 8-183566

1

【特許請求の範囲】

【請求項 1】 破断伸び率 500%以上、永久歪み 20%以下の特性を有するゴムからなる医療用具を、当該ゴムの破断伸び率 20%以上に伸長された状態で保持し、酸素ガス透過度が $1 \text{ cm}^3 / \text{m}^2 \cdot \text{atm} \cdot 24 \text{ hr}$ 以下の素材からなる包装容器もしくは包装袋に収納し、密封することを特徴とするゴム製医療用具の包装方法。

【請求項 2】 包装容器もしくは包装袋内の空気を不活性ガスで置換することを特徴とする、請求項 (1) 記載のゴム製医療用具の包装方法。

【請求項 3】 包装容器もしくは包装袋内の空気を排出し真空包装とすることを特徴とする、請求項 (1) 記載のゴム製医療用具の包装方法。

【請求項 4】 請求項 (1) に記載された伸長された状態のゴム製医療用具を、酸素ガス透過度が $10 \text{ cm}^3 / \text{m}^2 \cdot \text{atm} \cdot 24 \text{ hr}$ 以下の素材からなる包装容器もしくは包装袋に収納すると共に、脱酸素剤を同封し、密封することを特徴とするゴム製医療用具の包装方法。

【請求項 5】 請求項 (1) に記載された伸長された状態のゴム製医療用具を、内容物のガス滅菌が可能なガス透過性の内袋に収納し、開口部を封止して、ガス滅菌を施した後、酸素ガス透過度の小さい外袋に収納することを特徴とする、請求項 (1) ないし請求項 (4) のいずれかに記載のゴム製医療用具の包装方法。

【請求項 6】 ゴム材料が、天然ゴム、イソブレンゴム、ブタジエンゴム、スチレン-ブタジエンゴム、ニトリルゴム、クロロブレンゴム、およびブチルゴムの中から選ばれた、1 種もしくは 2 種以上の組み合わせからなることを特徴とする、請求項 (1) ないし請求項 (5) のいずれかに記載のゴム製医療用具の包装方法。

【請求項 7】 ゴム製医療用具が、予め 200%以上に延伸、拡張して管状体の外周に装着し、内視鏡的に静脈瘤を結紮する静脈瘤結紮術に使用されるリングであることを特徴とする、請求項 (1) ないし請求項 (6) のいずれかに記載のゴム製医療用具の包装方法。

【発明の詳細な説明】

【0001】

【産業上の利用分野】 本発明は、伸長された状態で保持されたゴム製医療用具の、保存性と性能維持に優れた包装方法に関するものである。

【0002】

【従来の技術】 医療用具は近年 READY-TO USE の製品、すなわちディスプレイ医療用具が盛んに使用されるようになり、これらはすでにメーカーの段階で滅菌され、医師など医療機関内で包装を開封すればそのまま手術、処置等に使用することができる。これらの医療用具は、通常のデリバリーで最低 2-3 ヶ月間程度の保存期間を必要とし、さらに救急的に使用されるものあっては、病院内である程度保管して非常事態に備えることが必要であり、最低でも 6 ヶ月、できれば 2 年以上

2

のシェルフライフをもつことが要求される。

【0003】 天然ゴムや合成ゴムは、一般的に酸素やオゾンの作用により劣化し、通常の包装方法では 2 年程度しか保存性を有しない。また一方、ゴムを伸長した状態に保ちながら保存することは、従来全くといってよいほど実例がなく、仮にそれが可能であったとしても、ゴムの劣化が速くなり 3-6 ヶ月程度しか保存し得ない。

【0004】 医療用具についても同様で、ゴムを延伸しない状態で供給される製品でも最長で 2 年の保証期間しか有さず、表面をシリコンまたはフッ素剤による処理、もしくは塩素化処理することにより、さらに保存期間を延ばすことが試みられているが、処理方法によってはゴムの性能低下、すなわち弾性の低下、永久圧縮歪みの増加など本来の性能を低下させることがあった。

【0005】

【発明が解決しようとする課題】 本発明は、従来問題となっていたゴムの劣化や性能の低下を起させる事なく、長期の保存を可能にする包装方法を提供しようとするもので、特に従来製品化しえなかった、ゴムの破断伸び率の 20%以上の伸長状態において、その保存性を 4-8 倍に向上させ、1 年以上性能を保持させることを可能にする包装方法を提供することを目的としたものである。

【0006】

【課題を解決するための手段】 即ち本発明は、破断伸び率 500%以上、永久歪み 20%以下の特性を有するゴムからなる医療用具を、当該ゴムの破断伸び率の 20%以上に伸長された状態で保持し、酸素ガス透過度が $1 \text{ cm}^3 / \text{m}^2 \cdot \text{atm} \cdot 24 \text{ hr}$ 以下の素材からなる包装容器もしくは包装袋に収納し、もしくは、酸素ガス透過度が $10 \text{ cm}^3 / \text{m}^2 \cdot \text{atm} \cdot 24 \text{ hr}$ 以下の素材からなる包装容器もしくは包装袋に収納すると共に、脱酸素剤を同封し、密封することを特徴とするゴム製医療用具の包装方法である。

【0007】 また、上記の方法による包装時に、包装容器もしくは包装袋内の空気を不活性ガスで置換し、あるいは、空気を排出し真空包装とすること、さらには、伸長された状態のゴム製医療用具を、内容物のガス滅菌が可能なガス透過性の内袋に収納し、開口部を封止して、ガス滅菌を施した後、酸素ガス透過度の小さい前記の外袋に収納する包装方法も本発明に含まれる。

【0008】 またさらには、予め 200%以上に延伸、拡張して管状体の外周に装着し、内視鏡的に静脈瘤を結紮する静脈瘤結紮術に使用されるリングを、本発明の方法により包装することは、本発明の具体的な好ましい実施例として含まれる。

【0009】 本発明において包装の対象となる医療用具を構成するゴム材料としては、天然ゴム、イソブレンゴム、ブタジエンゴム、スチレン-ブタジエンゴム、ニトリルゴム、クロロブレンゴム、およびブチルゴムの中から選ばれた単体、もしくはそれらの 2 種類以上の組合

(3)

特開平8-183566

3

わせて用いられ、さらに場合によっては、これらを主成分としNBR、SBR、シリコーンゴム等が配合されていてもよい。

【0010】ここで用いられるゴムとは、通常にいわれるいわゆるゴム弾性体、即ちStress Strain Curveでヒステリシスがなく、その経時的回復力が瞬間的に90%以上回復するようなゴム弾性体であって、破断伸び率は500%以上、好ましくは700%以上の伸びを有するものが好ましい。また、永久歪みは20%以下、好ましくは15%以下の低永久歪率を有する天然ゴムもしくは合成ゴムであればよい。

【0011】更に、このようなゴムよりなる医療用具は、破断伸び率の少なくとも20%以上、場合によっては50%以上、もしくは少なくとも100%以上、場合によっては250%以上伸長された状態に保持され、実際に使用される際には、保持状態を開放したとき、瞬時にほぼ元の伸長前の状態に戻るものである。その例としては、例えば食道静脈瘤、ポリープ、ガン病巣等の結紮に用いるリングや、ゴムを動力とした引き金等の用途に使用されるものが挙げられる。

【0012】食道静脈瘤の結紮は、内径1.5~2.5mm、外径2.5~7.0mm程度のゴム製リングを、直径6~15mmに伸長させた状態で、内視鏡の先端に取りつけられた筒状のデバイスに装着し、デバイス内に吸引した静脈瘤にデバイスからリングを突き落として、吸引されてポリープ状になった静脈瘤の根本部に掛け、リングのゴムの収縮力で機械的に結紮する施術である。

【0013】通常の医療用具は、製造時にEOG（エチレンオキサイドガス）によって滅菌を行なうため、少なくとも包装の一部にガスが透過できる通気性を持った材料を用いることが必要である。従って、このような包装形態で伸長したゴム製リングを包装すると、約3ヶ月でリングの表面にクラックが生じ、場合によっては、医師の処置中にリングが切れて、大きな事故につながる危険性がある。

【0014】伸長された状態で保持されたゴムの劣化を防止するには、酸素ガス透過度 $1\text{cm}^3/\text{m}^2 \cdot \text{atm} \cdot 24\text{hr}$ 以下の酸素ガスバリア性の素材からなる包装容器もしくは包装袋を用いるのが有効である。また合せて、包装容器または袋内の空気を窒素ガス等の不活性ガスで置換し、あるいは、空気を排出して剛真空包装にすれば、一層効果が高まる。

【0015】酸素ガス透過度が $1\text{cm}^3/\text{m}^2 \cdot \text{atm} \cdot 24\text{hr}$ 以下の酸素バリア性包装材料としては、ポリビニルアルコール系フィルム、ポリ塩化ビニリデンフィルム等の単体、又はラミネートフィルムが挙げられる。また、シリカ蒸着ポリエチレンテレフタレートフィルムや、シリカ蒸着ポリ塩化ビニリデンフィルムも同様に有効である。アルミ箔複合フィルムやアルミ蒸着フィルムも同様

4

の効果を有するが、ものによっては透明性が損なわれることがある。

【0016】また、酸素ガス透過度が $10\text{cm}^3/\text{m}^2 \cdot \text{atm} \cdot 24\text{hr}$ 以下で、やや大きい酸素ガス透過性を有する素材からなる包装容器もしくは包装袋を使用する場合は、これに脱酸素剤を併用する方法で同様の効果が得られ、所期の目的を達することができる。さらに、包装容器または袋内の空気を不活性ガスで置換し、あるいは真空包装を併用すればより効果の高まることは勿論である。

【0017】酸素ガス透過度が $10\text{cm}^3/\text{m}^2 \cdot \text{atm} \cdot 24\text{hr}$ 以下の包装材料としては、ポリ塩化ビニリデンをコートし、もしくはポリビニルアルコールを複合したポリプロピレンやポリエステルフィルム、塩化ビニルやナイロンの単体フィルム、あるいはポリエチレンテレフタレートやナイロンにシリカを蒸着したフィルムや、これらを組合せた多層フィルムが挙げられる。また、袋状のものの場合には、これらにポリエチレン、EVA等のヒートシール性の良い樹脂を内側にラミネートしてあってもよい。その例としては、ポリエチレンテレフタレートまたはポリビニルアルコールと、ポリエチレンとの多層フィルムで、その間にシリカの蒸着層を設けたフィルム等がある。

【0018】次に、本発明で用いる脱酸素剤としては、活性酸化鉄を主成分にしたものが挙げられるが、特にこれに限定しない。活性酸化鉄の場合、1g当たり 22cm^3 の酸素吸収量があり、酸素濃度を21%とすると包装体の容積に対して $0.005\text{g}/\text{m}^3$ 以上の脱酸素剤の量であればよいが、包装材料の酸素透過度なども考慮してやや多めにしたほうが好ましく、 $0.007\text{g}/\text{m}^3$ 以上の脱酸素剤を包装体内に封入するのがよい。

【0019】これらの包装は袋状もしくはプリスターバック等、完全密封状態でなされることが必要で、さらにディスポーザブル医療用具の場合、滅菌されていることが必然である。従って、医療用具を包装容器もしくは包装袋に収納し、EOG等により通常のガス滅菌を行なう場合は、医療用具を少なくとも一部がガス透過性の素材で構成されていて、ガス滅菌が可能な内袋に収納し、ガス滅菌を施した後、酸素ガス透過度の小さい外袋に収納する、二重包装にすることが必要になる。

【0020】尚、 γ 線や電子線による滅菌を行なう場合は、ガス透過性包装の必要がなく、本願第一の発明による一段包装で十分である。 γ 線や電子線を照射するとオゾンが発生が起きるが、脱酸素剤を封入しておけば、その効果によりオゾンが吸収され、ほとんどゴムの劣化が起こらない事も判明しており、包装方法としてはより簡便である。

【0021】

【実施例】ポリエチレンテレフタレート $12\mu\text{m}$ /シリカ蒸着層/ポリエチレン $60\mu\text{m}$ の構成によるフィルム

(4)

特開平8-183566

5

(酸素ガス透過度 $1 \text{ cm}^3 / \text{m}^2 \cdot \text{atm} \cdot 24 \text{ hr}$ 以下) を用いたシリカ蒸着袋に、内径 2 mm でイソプレンゴム製のリングを、600%に伸長した状態でガス透過性の袋に収納しガス滅菌したものを入れ、密封して二重包装とした。これをオゾン50pphm、温度40℃の環境下に放置したところ、72時間後でもリング表面にクラック等は生じなかった(空气中、3年間保存に相当)。また、空气中で2年間保存する長期保存試験を行ったが、リング表面にクラック等は生じなかった。シリカ蒸着袋による酸素遮断の効果が明らかである。

【0022】

6

【比較例】600%に伸長した実施例と同じリングを、ガス透過性を有する紙製の滅菌袋に収納し、空气中で保存した。1ヶ月後には、リング表面にクラックが生じ、一部が切れかかった状態となり、空气中のオゾンまたは酸素の作用により、急速に劣化が進むことが分かる。

【0023】

【発明の効果】本発明の包装方法を用いてゴム製医療用具を包装することにより、オゾン等によるゴムの劣化を防止する事ができ、長期間の保存を可能にすると共に、品質の安定化を図ることが出来る。